



PRESS RELEASE For Immediate Release

Wenzel Spine Announces FDA 510K Clearance

Wenzel Spine Gains 510K clearance to market the VariLift® Stand-Alone Expandable Interbody Fusion System

AUSTIN, TX September 29, 2010 – Wenzel Spine, Inc., a medical device company focused on offering less invasive, stand-alone alternatives to traditional spinal fusion, today announced they have received 510K clearance to market the VariLift Expandable Interbody Fusion System.

Wenzel Spine received clearance from the Food and Drug Administration (FDA) to market the VariLift System as an Interbody Fusion Device for stand-alone use. The VariLift Interbody Fusion System (VariLift-L and VariLift-A) is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Chad Neely, the CEO of Wenzel Spine, said, “We are pleased that the FDA granted clearance to market the VariLift Expandable Interbody Fusion System without the need for pedicle screws. This will be an interesting lumbar fusion option for spine surgeons to offer to their patients. Additionally, the minimally invasive techniques that the product’s design allows are an exciting option we will begin to explore with interested surgeons.”

VariLift-L is designed to be implanted as a single device via a transverse (TLIF) approach or bilaterally via a posterior (PLIF) approach. VariLift-A is designed to be implanted bilaterally via an anterior (ALIF) approach. VariLift-L and VariLift-A may be implanted with or without supplemental fixation and are intended for use with autograft to facilitate fusion.

Mr. Neely added, “Proven stand-alone solutions like VariLift that don’t require supplemental fixation are essential for today’s surgeons and patients. VariLift is one of the original zero-profile spine implants, a design philosophy that has gained favor of late. Its expansion feature, in particular, has allowed it to garner outstanding clinical results over the last 10 years in thousands of patients.”

Wenzel Spine’s VariLift® Stand-Alone Expandable Interbody Fusion System is now commercially available in North America and Europe.



About Wenzel Spine, Inc.

Wenzel Spine offers minimally invasive solutions for stand-alone treatment of disc herniations, spinal stenosis, and spondylolisthesis. We deliver simple, dependable, and proven alternatives to traditional interbody spinal fusion, including the patented VariLift® Expandable Interbody Fusion System. Our products help simplify and shorten spine surgery, while providing excellent clinical patient outcomes. Wenzel Spine is dedicated to improving the overall quality of spine care, while reducing the cost to health care providers. For more information about the Wenzel Spine and our products, visit www.wenzelspine.com.

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